

## **REMARKS/ARGUMENTS**

In the specification, the Abstract has been corrected by capitalizing and italicizing *Lactobacillus*.

In the specification, Paragraph [0007] has been corrected to change the spelling of “lie” to tied.

In the specification paragraphs [0012], [0013] and [0014] have been cancelled. These paragraphs were repeats of other paragraphs in the Background.

Paragraph [0018] has been corrected by changing the spelling of “mater” to matter.

Paragraph [0019] has been corrected by changing the spelling of “sent” to present.

Paragraph [0021] has been corrected by changing the spelling of “ermine” to enzymes.

Paragraph [0022] has been corrected by capitalizing and italicizing *Lactobacillus*.

Paragraph [0028] has been corrected by putting the names of bacteria in italics, capitalizing the first letter of the genus name and using lower case for the first letter of the species name.

Paragraph [0029] has been corrected by capitalizing and italicizing *Lactobacillus*.

Paragraph [0030] has been corrected by putting the names of bacteria in italics, capitalizing the first letter of the genus name and using lower case for the first letter of the species name.

Paragraph [0031] has been corrected by putting the names of bacteria in italics, capitalizing the first letter of the genus name and using lower case for the first letter of the species name. The word “four” has also been corrected to fourth.

Paragraph [0035] has been corrected by putting the names of bacteria in italics, capitalizing the first letter of the genus name and using lower case for the first letter of the species name.

Paragraph [0036] has been corrected by putting the names of bacteria in italics.

Paragraph [0041] has been corrected by putting the names of bacteria in italics.

The new paragraph [0051.1] has been added after paragraph [0051]. Table 6 for some reason had been placed in paragraph [0057].

Paragraph [0057] has been amended by removing Table 6 and placing Table 6 in new paragraph [0051.1].

Claims 1-9, 19 and 22 remain in this application. Claims 10-18, 20 and 21 have been withdrawn. Claims 1-9 and 19 have been amended to avoid the Mann reference cited by the Examiner. Claims 10-18, 20 and 21 have been withdrawn as a result of an earlier restriction requirement.

In view of the Examiner’s earlier restriction requirement, applicants retain the right to present Claims 10-18, 20 and 21 in a divisional application.

The Examiner pointed out that the Hutchinson reference listed in the Background of the Invention was not properly identified on the IDS form. I submitted a paper form of the reference with my IDS form when I filed the application. An additional paper form of the reference is included with this filing.

Reconsideration is respectfully requested of the objection to claims 1, 3, 6, 9 and 19 on the grounds that the species name should be capitalized and should be in italics and the genus name should not be capitalized and should be in italics. This has been corrected in the claims and throughout the specification.

Reconsideration is respectfully requested of the rejection of Claims 1-9 and 22 under 35 U.S.C. 112, second paragraph as being indefinite.

In claim 1 “at least about” has been changed to “at least”.

Claim 2 has been made independent. A fee has been paid for additional independent claims which are now withdrawn.

The term “protein byproducts” which the Examiner contended had no antecedent basis, has been deleted from Claim 6.

In claims 5 and 22 the step of replacing the by-pass or by-product protein, which the Examiner contends is indefinite, has been removed from the claims.

Reconsideration is respectfully requested of the rejection of claim 1-9, 19 and 22 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.

The specification discloses:

[0037] Enzymes that can be used in the practice of the present invention are available from NOVOZYMES JEFFREYS BIOLOGICALS, Inc. Salem, Va. in products known as Xylanase, Maxicel.TM., Multicel.TM. and EX 28000.TM. enzymes.

[0038] Xylanase acts on D-Xylan in a manner reminiscent of alpha and beta amylase on starch and results in the production of D-Xylose. Due to interactions with pectin and hemicellulose, Xylanase has a considerable amount of pectinase added. The activity is 30,000 to 150,000 Xylanase Units/g. This product also contains high levels of cellulase, pentosanase and petinase.

[0039] Many cellulases of fungal origin are known for their activity range extending well into the lower pH values. Maxicel and Multicel are two such companion products with very concentrated cellulolytic activity.

[0040] Multicel.TM. 185 cellulase is a combination of cellulases from *Aspergillus oryzae*, *Trichoderma viride* and *Aspergillus niger*. Multicel 185 has a cellulase activity, at pH 6.5, of 185,000 units/g. Assay Method: C.sub.1-ase as well as CMC-ase. Multicel also has some xylanase activity.

[0041] EX 28000 enzymes product is a water dispersible blend of the extracts of *Bacillus subtilis* and *Aspergillus oryzae*. The product includes high concentrations of alpha-amylase, beta-glucanase (gumase), and hemi-cellulase. The product has an Amylolytic Activity of

28,000 BAU/gram, a Betaglucanase Activity of 12,000 Betaglucanase units/gram and a Hemicellulase Activity of 900 Hemicellulase units/gram, Although a primary enzyme associated with *Bacillus subtilis* exact is amylase, other useful hydrolases are often included in this product. These other enzymes catalyze the breakdown of complex carbohydrates other than starch. Hemicellulase activity attacks plant wall components. Beta-glucanase helps break down beta-linked glucose polymers often associated with grains, such as barley, oats, and wheat, and other products, including soy bean meal and locust bean gum. This additional digestive action is broadly classified as gumase activity. The presence of soluble calcium has a stabilizing effect on most enzymes of this type.

The following was copied from a recent advertisement by Novozymes:

Animal Feed, Internet, retrieved on June 1, 2009, retrieved from [www.novozymes.com/en/main\\_structures/ProductsAndSolutions/animal\\_feed/Animal\\_feed](http://www.novozymes.com/en/main_structures/ProductsAndSolutions/animal_feed/Animal_feed) "A wide range of enzyme preparations are available from Novozymes, the leading supplier of enzymes to the animal feed industry. Our enzymes degrade substances such as phytate, glucan, starch, protein, pectin-like polysaccharides, xylan, raffinose and stachyose."

Also submitted with this amendment are the product data sheets for EX 14000, EX 28000, Multicell 185 and XYLANASE. These product data sheets disclose the method of analysis and stability vs time of the enzymes.

Reconsideration is respectfully requested of the rejection of claim 22 under 35 U.S.C. 112 first paragraph. The Examiner points out that claim 22 fails to include *Lactobacillus*. The claim has been corrected.

Reconsideration is respectfully requested of the rejection of claims 1-8, 19 and 22 under 35 U.S.C. 102(b) as by clearly anticipated by WO 96/17525 [N].

The Examiner cites the reference as teaching administering two or more of a) an obligate anaerobe, b) a facultative anaerobe such as lactic acid bacteria and c) one or more enzymes---

The claims have been amended to recite that the bacteria and enzymes added consist essentially of *Lactobacillus* and enzymes. This claim language excludes the presence of an obligate anaerobe. The restriction finds support in the fact that our disclosure does not include anything that would materially effect our combination of enzymes and bacteria. The enzymes and bacteria and their amounts are disclosed in paragraphs [0028]-[0032]

Reconsideration is respectfully requested of the rejection of claims 1-8, 19 and 22 under 35 U.S.C. 103(a) as being unpatentable over WO 96/17525 [N].

The Examiner cites the reference as teaching administering two or more of a) an obligate anaerobe, b) a facultative anaerobe such as lactic acid bacteria and c) one or more enzymes---

The claims have been amended to recite that the bacteria and enzymes added consist essentially of *Lactobacillus* and enzymes. This claim language excludes the presence of an obligate anaerobe.


Mann at page 5, lines 15 through 25 states "The maintenance of the desired condition of the rumen may be achieved by the addition of one or more organisms that are normally found in the rumen. For example the reestablishment of fiber digestion can be achieved by the addition of ruminal fibre-degrading bacteria and fungi. However the ruminal pH must first be raised to a pH close to 6.5 and maintained there before this can be done. This can be achieved by adding one or more organisms capable of metabolizing lactic and other acids.

The claims of the present invention exclude the addition of one or more organisms listed by Mann as capable of metabolizing lactic and other acids.

The REQUIREMENT UNDER 37 CFR 1.105 has been complied with via the attached declaration.

There are no copending applications.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 6 June 2009,



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## PRODUCT DATA SHEET

### EX 14000

**PRODUCT:** A water dispersible blend of the extracts of *Bacillus subtilis* and *Aspergillus oryzae*, which includes high concentrations of alpha-amylase, beta-glucanase (gumase), and hemicellulase which is also reflected in xylanase activity.

**PURPOSE:** As a concentrated source of hydrolytic (degrading) carbohydrase enzymes which may be used in enzyme bearing products and supplements where increased enzyme activity is desired on starch and non-starch polysaccharide substrates.

**STATUS:** GRAS Animal Feed Ingredient. American Association of Feed Control Officials definition: 36.6 Dried *Bacillus subtilis* Fermentation Extract. Dried *Aspergillus oryzae* Fermentation Extract.

#### ANALYSIS:

Amylolytic Activity:	14,000 B.A.U./gram
Betaglucanase Activity:	9,000 Betaglucanase units/g
Hemicellulase Activity:	1,000 Hemicellulase units/g

**METHOD OF ANALYSIS:**—Modified FCC, AATCC (ANSI) Method

**APPEARANCE:** Light tan, free flowing granular powder

**STORAGE CONDITIONS REQUIRED:** For optimal activity over longest storage time keep in dry warehouse under 110° F. Half life under these conditions estimated to be in excess of two years.

**PRECAUTIONS:** Presence of calcium will help improve temperature stability of these products. See Material Safety Information for further data as to the safe handling of enzyme concentrates.

**PACKED IN:** 50 lb, 25 KG, or 65 lb fiber drums.

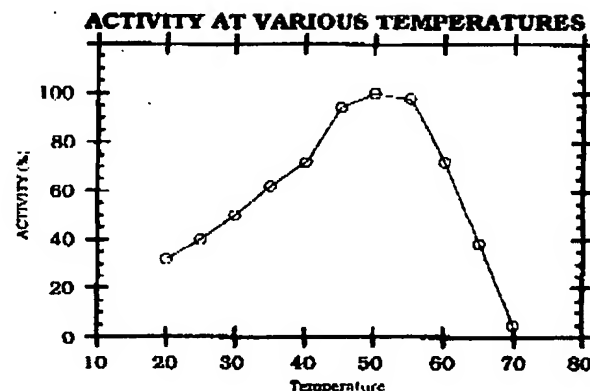
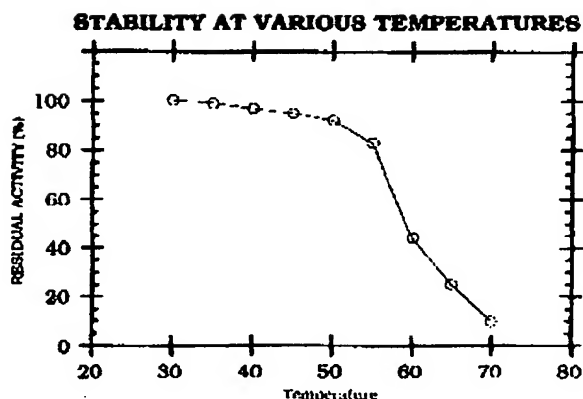
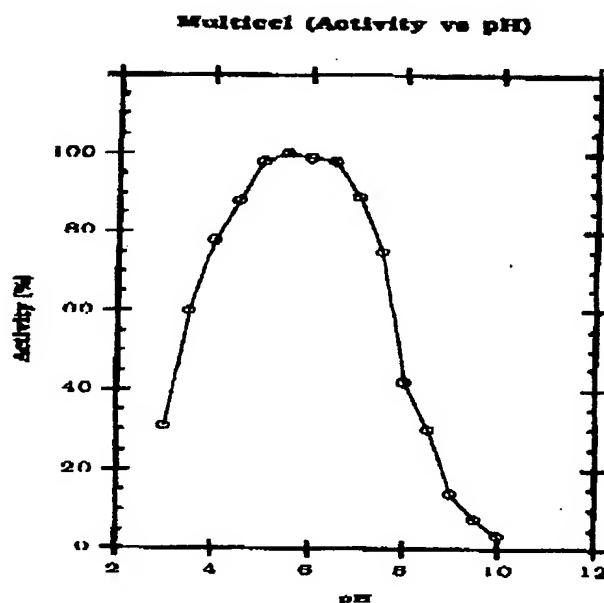
**USE RATE:** Ask for specific recommendations as to product for use in industrial, or agricultural applications.

#### FOR MANUFACTURER'S USE ONLY

All data and suggestions made herein are based upon our research or published data and are believed to be accurate. However, no guarantee or warranty is made or implied as conditions and methods of use of products herein described are variable. This information and products, if any, are provided on the condition that the user will evaluate them for himself, as well as any formulae or recommendations, to determine their suitability for his own purposes before adoption. Also, statements as to the use of products herein described are not to be construed as recommendations for their use in infringements of any patents.

SPECIALTY PRODUCTS FOR INDUSTRY & AGRICULTURE

Revision: 691-2

*Product: Multicel**Page 2*

Many cellulases of fungal origin are known for their activity range extending well into the lower pH values. Their broad, nonspecific nature makes them useful in a variety of industrial and agricultural applications. Maxicel and Multicel are two such companion products with very concentrated cellulolytic activity.

Maxicel is a broad spectrum cellulase that is the product of choice particularly use for cleaning and for certain other industrial applications. Both Multicel and Maxicel's rapid attack of a great variety of native

cellulosic materials and their stability give the products particularly desirable characteristics for many fiber processing uses. Unlike many other cellulases of fungal origin, these products do not require acidic pH adjustment for optimal activity.

While both products have similar pH and temperature optima, Maxicel is more compatible with a variety of surfactants and detergent compounds and has very good stability in alkaline and diluted aqueous solution. Multicel has broader pH range of efficacy and greater reducing capacity.

# JEFFREYS

# Product Data:

George A. Jeffreys and Company, Inc.  
*Applied Biotechnology*

INDUSTRIAL/AGRICULTURAL  
GRADE CELLULASE

ENZYMES & FERMENTATION PRODUCTS

# JEFFREYS

## Multicel 185

**DESCRIPTION:** A special granular cellulase preparation which is produced for a variety of applications including agricultural processes, for native fibersolubilization, fiber dewatering/filtration, digestion of cellulosic material and even enhancement of waste treatment. This enzyme product can be used for a great number of other industrial applications as well. Unlike many fungal cellulases that are available commercially, this product has a very broad pH range of activity and action patterns suitable for use on all types of modified and native cellulosic materials. This product is a combination of cellulases from *Trichoderma viride*, *Aspergillus oryzae* and *Aspergillus niger*.

**PURPOSE:** As a concentrated source of hydrolytic (degrading) enzymes which may be used in industrial and agricultural applications, including for use in waste treatment enhancement products, in compounds for industrial cleaning and maintenance, and in many other applications where broad range cellulolytic enzyme activity is desired.

**ANALYSIS:** 185 units/mg (185,000 units/gram)

cellulase activity at pH 6.5

**pH OPTIMUM:** 5.0- 7.5, Activity range: pH 4.0 - 9.5

**ASSAY METHOD:** C<sub>1</sub>-asc as well as CMC -ase activity measured and standardized.

**APPEARANCE:** Off white, free flowing granular powder, slight odor

**STORAGE CONDITIONS:** For optimal activity over longest storage time, keep in dry warehouse under 100° F. Half life under these conditions estimated to be in excess of one year.

**PRECAUTIONS:** See above (storage conditions); avoid inhalation of dust of all concentrated enzymes (always wear approved dust masks) as they may elicit allergic reactions from susceptible individuals. Handle only after consulting material safety information sheet.

**PACKAGE SIZES:** 35, 75, and 150 lb polyethylene-lined drums

## FOR MANUFACTURER'S USE ONLY

All data and suggestions made herein are based upon our research or published data and are believed to be accurate. However, no guarantee or warranty is made or implied as conditions and methods of use of products herein described are variable. This information and products, if any, are provided on the condition that the user will evaluate them for himself, as well as any formulae or recommendations, to determine their suitability for his own purposes before adoption. Also, statements as to the use of products herein described are not to be construed as recommendations for their use in infringements of any patents.



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Revision: 7964



*Product Used*

## PRODUCT DATA SHEET

### EX 28000

**PRODUCT:** A water dispersible blend of the extracts of *Bacillus subtilis* and *Aspergillus oryzae*, and which includes high concentrations of alpha-amylase, beta-glucanase (gumasc), and hemi-cellulase.

**PURPOSE:** As a concentrated source of hydrolytic (degrading) enzymes which may be used in enzyme bearing supplements where increased enzyme activity is desired.

**STATUS:** GRAS Animal Feed Ingredient. American Association of Feed Control Officials definition: 36.6 Dried *Bacillus subtilis* Fermentation Extract, Dried *Aspergillus oryzae* Fermentation Extract. Enzymes are also covered by other appropriate sections of the *Official Publication*.

#### ANALYSIS:

Amylolytic Activity: 28,000 BAU/gram  
Betagluconase Activity: 12,000 Betagluconase units/g  
Hemicellulase Activity: 900 Hemicellulase units/g

**METHOD OF ANALYSIS:** —Modified FCC, AATCC (ANSI) Method

**APPEARANCE:** Light tan, free flowing granular powder; yeasty, fermentation odor

**STORAGE CONDITIONS REQUIRED:** For optimal activity over longest storage time, keep in dry warehouse under 110° F. Half life under these conditions estimated to be in excess of two years.

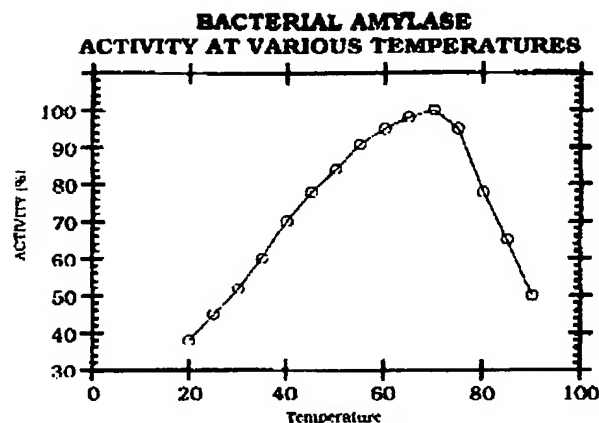
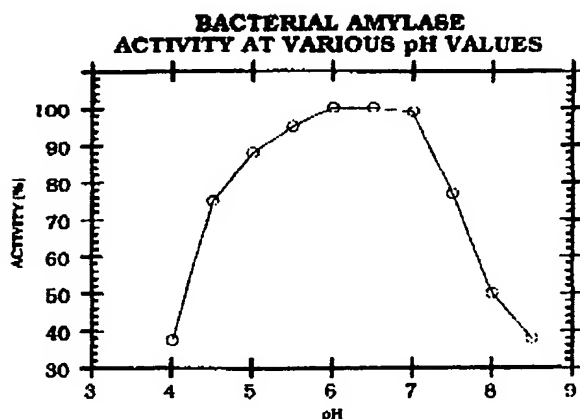
**PRECAUTIONS:** See above (storage conditions), see material safety data sheet for general information concerning enzymes. Avoid use in extremely dusty environment; concentrate may cause allergic reactions in certain susceptible individuals, as with many other feedstuffs. Many of these enzymes will normally survive pelleting. Care should be used to insure that minimum of steam is used and that aftercoolers are working properly to guarantee maximum enzyme potency in the final product. Presence of calcium will help improve temperature stability of these products.

**PACKED IN:** Polyethylene lined, fiber drums in several metric and English net content measurements

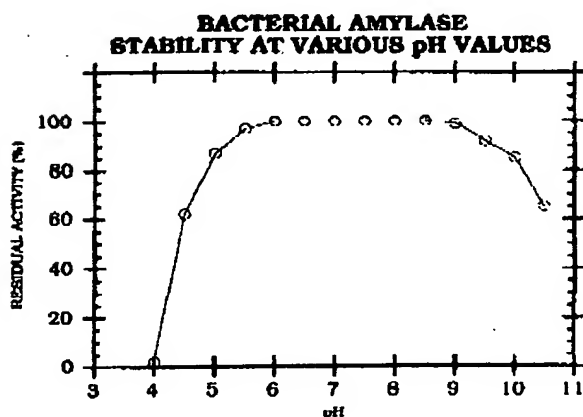
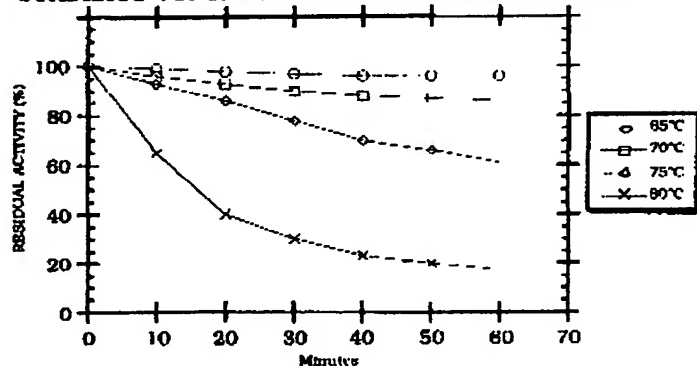
**FOR MANUFACTURER'S USE ONLY**

Product: EX 24,000

Page 2



**BACTERIAL AMYLASE  
STABILITY VS. TIME AT VARIOUS TEMPERATURES**



*Bacillus subtilis* amylase is particularly useful in industrial and agricultural processing applications due to its high degree of stability. This enzyme's resistance to denaturation by temperature and pH extremes make it particularly durable. This endo-acting amylase very rapidly dextrinizes starch components bypassing branch points which often serve as blocking points to other exo-acting amylases including glucoamylase. *Bacillus subtilis* amylase is particularly useful due to its activity upon a broad range of starches. Although a primary enzyme associated with *Bacillus subtilis* extracts is amylase, other useful hydrolases are often included in these products. These other enzymes catalyze the breakdown of complex carbohydrates other than starch. Hemi-cellulase activity attacks plant wall components. Beta-glucanase helps break down beta-linked glucose polymers often associated with grains, such as barley, oats, and wheat, and other products, including soy bean meal and locust bean gum. This additional digestive action is broadly classified as a gumase activity. The presence of soluble calcium has a stabilizing effect on most enzymes of this type.



Revision: 691-1

# XYLANASE

## DESCRIPTION

Plant cell walls consist of large amounts of cellulose microfibrils embedded in a continuous phase of lignin, pectin and hemicellulose, with the hemicellulose fraction predominating. These non-starch polysaccharides are primary components of grains and grain products such as wheat, barley, and corn cobs (up to 50% hemicellulose). Animal feeds frequently incorporate these hard to digest products. Considerable interest has developed in trying to break down the hemicellulose (xylan) portion to increase feed efficiency.

Xylanase acts on D-Xylan in a manner reminiscent of alpha and beta amylase on starch and results in the production of D-Xylose. Due to interactions with pectin and hemicellulose, Xylanase has a considerable amount of pectinase added.

Starch, proteins, and cellulose often become intertwined with hemicellulosic gums in the digestive tracts of both monogastrics and ruminants. Enzymatic and bacterial action native and crucial to the digestive process cannot occur due to physical hindrance by the gums. The inability of digestive enzymes and native bacteria to come in contact with substrate leads to a loss in feed efficiency.

## CHARACTERISTICS

### APPEARANCE:

Tan powder

### ACTIVITY:

100,000 U/g

150,000 Xylanase Units/g Will blend to customer's specifications. This product also contains high levels of: cellulase, pentosanase and pectinase.

### UNIT DEFINITION:

Defined as 100 units when 1 mg of reducing sugar equivalent to xylose is produced in 1 ml under the conditions of the assay.

### OPTIMUM pH:

3.0 - 4.0 very stable from pH 2.0 to 7.0.

## APPLICATION RATES

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## STORAGE AND PACKAGING

Please inquire about our available packaging options.

This product should be kept in a cool dry location. The drum should be kept closed when not in use. Exposure to high humidity and temperature is not recommended.

## HANDLING

Please refer to the Material Safety Data Sheet and the Enzyme Technical Association publication *Working Safely With Enzymes*.